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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/866,232	05/25/2001	Luis Tomas Sorell Gomez	976-10	5854

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EXAMINER

NGUYEN, BAO THUY L

ART UNIT PAPER NUMBER

1641

DATE MAILED: 02/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/866,232

Applicant(s)

SORELL GOMEZ ET AL.

Examiner

Bao-Thuy L. Nguyen

Art Unit

1641

-- Th MAILING DATE of this communication appears on th cov r sh t with the correspond nce address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
  - 2) ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Priority*

1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### *Claim Rejections - 35 USC § 112*

2. Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are directed toward a method to detect transglutaminase IgA or IgG in a sample using a solid support. The solid support appears to have at least two different zones that are in fluid contact promoting a lateral flow of the reactants. The claims recite that the IgA or IgG in the sample is allowed to form a complex with labeled-transglutaminase antigens, and the complex is then allow to react with an unlabeled transglutaminase antigen immobilized in a reaction zone, promoting its deposition on this zone (i.e. the complex is capture by the immobilized antigen, presumably via binding of the unlabeled antigen with the antibody).

Although no detection step is recited, it is assume that detection of the label in the reaction zone correlates to the presence or amount of transglutaminase IgA or IgG in the sample. Such a method does not appear to work as claimed. It is unclear how the binding sites on the transglutaminase IgA or IgG in the same is prevented from being saturated with the labeled antigen leaving available binding sites to bind to the unlabeled, immobilized antigen. In the event that the binding sites on the IgA or IgG are saturated by labeled antigen, the entire

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complex flow past the reaction zone and no label is detected, leading to a false negative result.

Although the specification recites an example where the assay is conducted, it cannot be determined from this example whether it is theoretic or if an actual reaction took place since no results are presented.

3. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it lacks a correlation between step b and any detection of the IgA or IgG.

Claim 1 is vague because it is unclear whether it is a competitive or sandwich assay. The recitation of the inert support and the zones on this support is vague since it appears, but is not positive recited, that the support has at least two different zones that are in fluid communication and that samples is allow to contact the labeled reagent zones and thereafter migrates to the reaction zone where any complex between the labeled reagent and the antibodies in the sample is captured.

Claim 1 is also vague and indefinite because it does not appear to work.

Claims 2-4 should be amended for clarity. It is recommended that "an assay to detect IgA or IgG anti-transglutaminase antibodies" be replace with -The assay--.

Claim 5 is confusing because it appears to lack antecedent support. It is unclear what "procedure" is referenced in this claim.

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*Conclusion*


4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,319,726  
US 2001/0036639  
WO 01/29090

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Bao-Thuy L. Nguyen  
Primary Examiner  
Art Unit 1641  
2/9/04